The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID S. UTTERBERG

Appeal No. 2000-1995 Application No. 08/850,277

HEARD: April 11, 2001

Before McCANDLISH, <u>Senior Administrative Patent Judge</u>, and COHEN and McQUADE, <u>Administrative Patent Judges</u>.

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

David S. Utterberg appeals from the final rejection of claims 1 through 8, 10 through 12 and 14 through 19, all of the claims pending in the application.

THE INVENTION

The invention relates to a hemodialysis pump set having branch line connectors designed to facilitate automated

packaging and subsequent set-up of the pump set, and to eliminate kinking

of the branch lines during use. Representative claim 1 reads as follows:

1. A set for conveying blood between a patient and blood treatment apparatus, which comprises:

blood flow tubing; a connector for connecting the tubing with a patient's vascular system; a connector for connecting the tubing with the blood treatment apparatus; a portion of said tubing comprising an enlarged-diameter, pump segment tubing connected at each pump segment tubing end with a pump tubing connector, each pump tubing connector also connecting in substantially straight-line relation to another portion of said blood flow tubing, at least one of said pump tubing connectors also connecting to a branch line in longitudinal relation to said other portion of the blood flow tubing wherein said set may be easily assembled and packaged in an automated manner.

THE EVIDENCE

The items relied on by the examiner as evidence of obviousness are:

Reed et al. (Reed) 3,944,261 Mar. 16, 1976 Utterberg 5,061,365 Oct. 29, 1991

¹ The following terms in the appealed claims lack a proper antecedent basis and are deserving of correction: "said connectors" (claims 2 through 4, 12 and 18), "said blood flow conduit" (claims 3, 12 and 16); and "said longitudinally connected branch lines" (claims 6 and 11).

The item relied on by the appellant as evidence of nonobviousness is:

The 37 CFR § 1.132 Declaration of David S. Utterberg filed November 9, 1998 (Paper No. 8).

THE REJECTION

Claims 1 through 8, 10 through 12 and 14 through 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Utterberg in view of Reed.

Attention is directed to the appellant's main and reply briefs (Paper Nos. 12 and 14) and to the examiner's answer (Paper No. 13) for the respective positions of the appellant and the examiner with regard to the merits of this rejection.²

DISCUSSION

Utterberg, the examiner's primary reference, discloses a hemodialysis arterial blood flow set 10 comprising a connector 12 for connecting the set to a patient, tubing 16, a negative

² The examiner's refusal to consider and respond to certain arguments advanced in the main brief because they allegedly were being presented for the first time (see page 7 in the answer) has no basis in USPTO practice.

pressure pillow 24 having an angled branch port 30 for a saline line 32, tubing 26, roller pump tubing 34, a connector having an angled branch port for a heparin line 38, tubing 36 and a connector 14 for connecting the set to a dialyzer, these components being arranged as shown in Figure 1.

It is not disputed that the Utterberg blood flow set responds to all of the limitations in independent claims 1, 5, 10, 14, 18 and 19 except for those requiring at least one of the pump tubing/segment connectors to connect to a branch line in "longitudinal" (claims 1, 5, 14 and 18) or "substantially parallel" (claims 10 and 19) relation to the associated portion of the blood flow tubing/conduit. As indicated above, the corresponding relation in the Utterberg blood flow set is angled (perpendicular as shown in the drawings).

Reed discloses a bifurcated tubing connector for an extracorporeal blood handling system, such as a hemodialysis system, wherein it is necessary to join two incoming blood streams into a single outgoing stream. Reed teaches that

³ The underlying specification (see, for example, pages 5 and 9) uses the terms "parallel" and "longitudinal" interchangeably to describe the relation between the branch lines and the associated blood flow tubing/conduits.

conventional "Y" and "T" connectors "pose serious problems inherent in their design in that they tend to subject the blood to hemolytic trauma. For example, blood hemolysis results when blood and its components are exposed to excessive turbulence, sharp corners and obstruction" (column 1, lines 19 through 24). To overcome these problems, Reed proposes a bifurcated tubing connector 10 having three tubing couplings 16, 18 and 20 which are in parallel relation to one another (see Figure 2).

In combining Utterberg and Reed to reject the appealed claims, the examiner concludes that it would have obvious to one of ordinary skill in the art "to provide the tubing set of

Utterberg with the bifurcated connector of Reed, in order to reduce the hemolysis of blood" (answer, page 5).

The flaw in the examiner's reasoning, however, is that neither reference indicates that hemolysis occurs in blood flow sets of the sort disclosed by Utterberg, let alone in the particular area at issue where the saline and/or heparin branch lines connect with the blood flow tubing/conduit.

Moreover, neither reference demonstrates any appreciation of

the particular problems posed by blood flow sets of the sort disclosed by Utterberg or the advantageous solutions thereto embodied by the claimed invention which are documented in the appellant's specification and in the Utterberg declaration. In this light, we are satisfied that the evidence before us does not justify the examiner's conclusion that the differences between the subject matter recited in independent claims 1, 5, 10, 14, 18 and 19 and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claims 1, 5, 10, 14, 18 and 19, or of dependent claims 2 through 4, 6 through 8, 11, 12 and 15 through 17, as being unpatentable over Utterberg in view of Reed.

As a final matter, upon return of the application to the technology center, the examiner may wish to consider whether U.S. Patent No. 5,360,395 raises a double patenting issue with respect to the claims in the instant application. According

to the record, the instant application is a continuation of Application 08/312,301, filed September 26, 1994, now abandoned, which was a continuation of Application 08/170,534, filed December 20, 1993, now the U.S. patent in question. The appellant submitted a terminal disclaimer in parent Application 08/312,301 in an apparent attempt to obviate any double patenting complication.

SUMMARY

The decision of the examiner to reject claims 1 through 8, 10 through 12 and 14 through 19 is reversed.

REVERSED

HARRISON E. McCANDLISH, Sen Administrative Patent Judge	•
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) BOARD OF PATENT
IRWIN CHARLES COHEN) APPEALS
Administrative Patent Judge	e) AND
) INTERFERENCES
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)
JOHN P. McQUADE)
Administrative Patent Judge	<u>)</u>

JPM/gjh

SEYFARTH SHAW 55 MONROE STREET SUITE 4200 CHICAGO, ILLINOIS 60603

GJH

Appeal No. 2000-1995 Application No. 08/850,277

APJ McQUADE

APJ McCANDLISH

APJ COHEN

REVERSED

HEARD: 3 PERSON CONFERENCE

September 12, 2002